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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,312	09/25/2006	Kevin Wickline	US040174US	6113
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EXAMINER				
GUPTA, VANI				
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3768				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/599,312

Applicant(s)

WICKLINE ET AL.

Examiner

VANI GUPTA

Art Unit

3768

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9 is/are allowed.
- 6) ☒ Claim(s) 1-8 and 10-18 is/are rejected.
- 7) ☒ Claim(s) 9 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date 9/25/2006

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. ***Claims 1, 10, 11, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Silverstein et al. (US 5,178,150).***

Regarding claims 1 and 10, Silverstein et al. discloses an ultrasonic probe comprising a transducer disposed at the distal end, wherein an ultrasound transducer (52) is enclosed within a fluid chamber/balloon (*flexible bag*, 62). Silverstein also discloses that the transducer is movably mounted within the fluid chamber; and a drive mechanism is coupled to the array transducer to move the array transducer during scanning (col. 6, line 35 – col. 7, line 38). Figure 4 depicts an arrangement of the transducer within the fluid-chamber-balloon combination.

Applicant should note that the transducer being an array transducer is an inherent arrangement for imaging transducers of ultrasonic imaging devices.

The coupling fluid within the fluid-chamber/flexible-bag is acoustic fluid 9col. 3, lines 14 – 16), and therefore, is inherently highly “transmissive” of ultrasound energy.

Furthermore, the fluid-chamber/flexible bag is a thin-walled compensation balloon in that it is compliant and can change shape, or expand. Since the fluid-

chamber/flexible bag and thin-walled compensation balloon are the one and the same, the thin-walled compensation balloon is inherently in "communication" with the fluid chamber.

Furthermore, since Silverstein et al. do not discuss heating or cooling the acoustic fluid, the acoustic fluid is inherently at nominal, or room, temperature (Abstract).

Furthermore, the balloon is formed of a substantially non-elastic material in that it is sufficiently compliant and can be placed against a surface of interest and will conform to that surface (col. 5, lines 64 – 67).

Regarding Claim 18, Silverstein et al. discloses that probe body of Claim 10 comprises a shaft designed for intracavity use of the probe (*endoscopic insertion tube*; col. 5, line 1; **fig. 1, 32**).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. *Claims 2 – 8 and 11 – 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silverstein et al. (US 5,178,150) in view of Lenz (US 7,479,128 B1).*

Regarding Claim 2, Silverstein et al. discloses an ultrasound probe comprising a thin-walled volume compensation balloon in communication with an acoustic fluid chamber that encloses a ultrasonic transducer.

Silverstein et al. differs from Claim 2 in that Silverstein et al. does not appear to specifically suggest that the balloon is formed of a non-elastomeric thermoplastic material.

However, Lenz teaches that thin-walled catheter balloon may be formed of non-elastomeric thermoplastic material (col. 4, line 43 – col. 5, line 61).

Accordingly, Lenz complements Silverstein et al. by teach a method of providing a protective coating on intravascular devices, especially dialation balloons, improving the durability of the device. Once the balloon is inserted in the cavity, it may be stretched to conform to the inner shape of the cavity, providing good coupling (col. 1, lines 6 – 8 and 12 – 15).

Therefore, it would be prima facie obvious to modify Silverstein with the teachings of Lenz to include materials for thin-walled volume compensation balloons to

obtain a polymeric, durable, scratch-, puncture-, and abrasion-resistant during the use of the balloon, to obtain the present invention in the instant Claim 2.

Regarding Claim 3, Lenz teaches that balloon may be formed of non-elastomeric thermoplastic material in such a way that the balloon exhibits low permeability to the acoustic fluid – one of ordinary skill in the art would be aware that “continuous coating of [the material]” means non-porous, or non-permeable (col. 3, lines 12 – 13).

Regarding claims 4 and 5 Lenz teaches that the balloon can be formed of non-elastomeric thermoplastic materials in such a way that the balloon would comprise properties such that it is capable of exhibiting high compliance over high and low temperature range; and exhibiting high thermal stability (col. 5, line 62 – col. 64).

Applicant should note that transporting, storing, using, and “operate[ing] at or below the glass transition temperature for the thermoplastic material” refers functional features and/or intended use and therefore does not limit the structure of the apparatus in such a way that it is novel over the prior art.

Furthermore, it would be obvious to one skilled in the art that imaging probes should comprise components formed of materials that are exhibit high compliance among a range of conditions within a variety of (even extreme) situations or scenarios.

Regarding Claim 6, utilizing acoustic fluid that comprises silicone oil is an obvious design choice because one of ordinary skill in the art would be aware that acoustic fluid that comprises oil-based components would provide lubrication to the

transducer components, therefore optimize performance of the rotational transducer of Silverstein et al.

Regarding Claim 7, Lenz teaches that non-elastomeric thermoplastic materials comprising PET polymers may be used to form the balloon (*col. 4, lines 43 – 50*).

Regarding Claim 8, Lenz teaches, via incorporation of *Wang et al.'s US Patent 5,830,182* (in *col. 4, line 66*) that the balloon material exhibits high burst strength (Wang et al.: *col. 7, lines 15 – 21*).

Regarding claims 11 and 12, lacking clarity, and lacking any unsolved problems or unexpected results, Silverstein et al. teaches that the balloon is approximately half filled with acoustic fluid at room temperature, wherein the balloon contains less than 20% of the fluid of the fluid chamber at room temperature.

Regarding claims 13 – 16, please refer to rejections of claims 2 - 5 and 7 – 9.

Regarding Claim 17, Lenz teaches, via incorporation of *US Patent 5,830,182* that the wall thickness of the balloon is less than 1.0 m (*col. 5, lines 25 – 26*). With respect to permeability characteristics of non-elastomeric thermoplastic materials, please refer to rejection of Claim 3.

Allowable Subject Matter

Claim 9 is allowed.

The following is a statement of reasons for the indication of allowable subject matter: the prior art neither teaches nor suggest "the thin-walled balloon of the ultrasonic probe exhibits a high compliance of less than 2 psi per ml; a low permeation

rate to acoustic fluid of less than 1.0; a high burst strength in excess of 10 atmospheres; *and* a thermal stability which does not significantly decrease compliance at low temperatures of operation".

Claim 9 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

2. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Wang et al. (US 5,738,901) for catheter with balloon coated with thermoplastic material.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VANI GUPTA whose telephone number is (571)270-5042. The examiner can normally be reached on Monday - Friday (8:30 am - 5:30 pm; EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-2083. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/V. G./
Examiner, Art Unit 3768

/Long V Le/
Supervisory Patent Examiner, Art Unit 3768